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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,491	05/30/2000	Kurt Hertogs	07691.0009	8312

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EXAMINER

GALITSKY, NIKOLAI M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,491

Applicant(s)

PAUWELS ET AL.

Examiner

Nikolai M Galitsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 8-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 8 sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 03/06/2002 have been fully considered but they are not completely persuasive. Any rejections not reiterated below have been withdrawn.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jon H. Condra et al. (Journal Of Virology, Dec 1996) and (Petropoulos et al., WO 99/67427, 29.12.99). This rejection is reiterated and maintained from the previous office action, mailed 12/04/2001, and as necessitated by amendment.

Note that the page 8270 2nd column; section (Primary viral isolates) states that IDV resistance with CIC 95c400nM, than Table 1 shows N88T has CIC95c3000nM in Patient O. The generic listing of mutation resistance in said Table 1 is deemed to motivate and suggest species therein such as mutant N88T. Step (i) of claim 7 is in the reference on page on page 73; line 4-5 (Petropoulos et al., WO 99/67427, 29.12.99). Step (ii) of claim 7 is as noted (Condra et al.) cohere HIV protease with mutation N88T correlate with a drug resistance. Step (iii) of claim 7 is shown in said Table 1 in that the presence of N88T was evaluated regarding effectiveness of a therapy.

Applicants argue that Table 1 of Condra merely lists all the mutations that were present in a patient isolate sample and relationship of that sample to resistance of indinavir.

The claimed invention is a method of evaluating the effectiveness of an antiviral therapy of an HIV infected patient. Examiner points out that in claim 7 (c) claimed "... at list one mutation chosen from 88T ...", which means the presence of said mutation in any combinations of mutations correlates with resistance to at least one PI. Condra et al noted on page 8270,

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“No single substitution was present in all resistant isolates, indicating that resistance evolves through multiple genetic pathways. Despite this complexity, all of 29 resistant isolates tested exhibited alteration of residues, suggesting of that screening of these residues may be useful in predicting the emergence of resistance. We also extended our previous finding that IDV-resistant viral variants exhibit various patterns of cross-resistance to a diverse panel of HIV-1 protease inhibitors. Finally, we noted an association between the number of protease amino acid substitutions and observed level of IDV resistance”.

Also, Condra et al notes on the page 8270 2nd column; section “ Primary viral isolates” (Condra et al.) states that IDV resistance with CIC 95c400nM, than Table 1 shows N88T has CIC95c3000nM in Patient O. The table 1 is including the species therein such as mutant N88T.

Step (ii) of claim 7 is as noted (Condra et al.) cohere HIV protease with mutation N88T correlate with a drug resistance. Step (iii) of claim 7 is shown in said Table 1 in that the presence of N88T was evaluated regarding effectiveness of a therapy.

That is clearly indicating the presence of N88T in any combination of mutants as responsible for resistance. It is noted that the process of evaluating the effectiveness of an antiviral therapy of an HIV infected patient is well known in the biochemical arts and thus supports this rejection in response to applicants arguments. Thus, this rejection is maintained and reiterated from the previous office action, mailed 12/04/2001.

The disclosure is objected to because of the following informalities:

On page 6 one hyperlink is objected to according form paragraph 7.29.04 Objection-embedded Hyperlinks or other Browser-Executable Code, because the “www....” hyperlink is still executable.

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Applicants are reminded that the descriptions of Figures 2a, 2b and 2c have to be separated, as each Figure must be separately described in the Brief Description of the Figures section.

Appropriate correction is required.

This application contains claims 1-6 and 8-30 are drawn to an invention nonelected with traverse in Paper No. ^{8, 11, 9/17/01.} ~~68~~. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. com. AM

No claim is allowed.

THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

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in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai M Galitsky, Ph.D., whose telephone number is (703) 308-2422.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Williams Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 17, 2002

NG

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER